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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT
OF CALIFORNIA

ERIN DUNCAN,

Plaintiff,

-against-

ALLERGAN, INC.; ALLERGAN USA, INC.; and ALLERGAN PLC,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Case No._____

COMPLAINT

COMES NOW, Plaintiff, by and through the undersigned counsel, and bring this complaint against Defendants and allege as follows:

1. This Complaint is brought on behalf of Plaintiff, ERIN DUNCAN, who suffered damages as a direct and proximate result of the negligent and wrongful misconduct of Defendants, ALLERGAN, INC., ALLERGAN USA, INC., and ALLERGAN PLC (hereinafter referred to as "Defendants") in connection with the research, testing, development, design, licensing, manufacture, packaging, labeling, distribution, sale, marketing, and/or introduction

into interstate commerce of Viberzi (eluxadoline). As a result of ingestion of Viberzi, Plaintiff ERIN DUNCAN (hereinafter referred to as "Plaintiff") was caused to suffer acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for future medical treatment and follow-up.

JURISDICTION AND VENUE

2. The Court has jurisdiction over this action pursuant to 28 U.S.C §1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and the Defendants as Defendants are all incorporated and have their principal place of business in states other than Plaintiff's home state of California.

3. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. §1367.

4. Further, a substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this district. Pursuant to 28 U.S.C. §1391, venue is proper in this district.

PARTIES:
PLAINTIFFS

5. Plaintiff is a citizen of the United States of America, and a resident of Burbank, California.

6. Upon information and belief, Plaintiff was prescribed, used and ingested Viberzi.

7. Upon information and belief, the injuries and damages sustained by Plaintiff were caused by Defendants' drug Viberzi.

8. Upon information and belief, Plaintiff read magazines, newspapers, and watched

television and other media, all of which communicated Defendants' Viberzi advertisements which minimized the risks of Viberzi and overstated its benefits and indications, all of which shaped Plaintiff's favorable perception of Viberzi.

9. As a result of using and ingesting Viberzi, Plaintiff was caused to suffer serious injuries.

PARTIES:
DEFENDANTS

10. Defendant Allergan, Inc. is a Delaware corporation having a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

11. Defendant Allergan USA, Inc. is a Delaware corporation having a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

12. Defendant Allergan PLC, is a foreign corporation with its principal place of business located at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland.

13. Upon information and belief, and at all relevant times, Defendants were engaged in the business of researching, testing, developing, designing, licensing, manufacturing, packaging, labeling, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Viberzi.

14. Upon information and belief, and at all relevant times, Defendants conducted regular and sustained business in California by selling and distributing its products in California, and engaged in substantial commerce and business activity in California.

FACTUAL BACKGROUND

15. This is an action against Defendants on behalf of Plaintiff, who was prescribed the drug Viberzi which is indicated for the treatment of irritable bowel syndrome with diarrhea.

16. Plaintiff ingested the prescribed dosage of Viberzi in accordance with the prescription written for Plaintiff.

17. Viberzi causes serious and sometimes fatal injuries including, but not limited to, acute pancreatitis and its sequelae.

18. At all times relevant herein, Defendants, either directly or through their agents, servants and employees, designed, manufactured, marketed, advertised, distributed and sold Viberzi for the treatment of irritable bowel syndrome with diarrhea.

19. Persons who were prescribed and ingested Viberzi, including Plaintiff, have suffered serious and permanent personal injuries.

20. Viberzi is a mu-opiod receptor agonist indicated in adults for the treatment of irritable bowel syndrome with diarrhea. It was approved for use in May 2015.

21. Acute pancreatitis is a sudden inflammation of the pancreas. Pancreatitis can cause serious complications, including infection, kidney failure, respiratory failure, diabetes and pancreatic cancer.

22. Acute pancreatitis is diagnosed by medical history, physical examination, and blood test for digestive enzymes of the pancreas (amylase and lipase). Imaging may also be utilized.

23. While acute pancreatitis may be suspected in patients with severe acute upper abdominal pain, a diagnosis cannot be established without biochemical or radiologic evidence.

24. Despite their collective resources, Defendants failed to fully and adequately test or research Viberzi and its association with pancreatitis to the detriment of Plaintiff, Viberzi users, the public, the medical community, and prescribing doctors.

25. Upon information and belief, Defendants failed to design and/or implement clinical trials that would capture and analyze data to determine the incidence of acute pancreatitis

in those patients with and without gallbladders.

26. Upon information and belief, Defendants did not require biochemical or radiological testing to confirm suspected instances of acute pancreatitis during clinical trials.

27. Upon information and belief, Defendants did not enforce required biochemical or radiological testing to confirm suspected instances of acute pancreatitis during clinical trials.

28. The lack of biochemical or radiological testing during the clinical trials led to undiagnosed instances of pancreatitis, resulting in misleading and inaccurate trial results.

29. For example, during the clinical trial phase, there were at least 40 instances of abdominal pain that led to trial discontinuation after starting Viberzi. Approximately half of those events occurred within 24 hours of Viberzi initiation. Of the approximately 40 with abdominal pain, the vast majority lacked biochemical or radiological testing to determine if the patient suffered from acute pancreatitis.

30. For example, during the clinical trial phase, there were 484 adverse events identified as possibly related to Sphincter of Oddi spasms (SOD). At least 47 lacked biochemical or radiological testing to determine whether the SOD clinical symptoms were actually instances of pancreatitis. Of the 484, only 37 were reviewed by a specialized committee. Of the 37, 18 (~half) were categorized as pancreatitis or biliary events. All 18 had taken Viberzi.

31. Properly designed and executed clinical trials would have led the original May 2015 label to contraindicate use in patients without gallbladders. Because the FDA did not have the benefit of data from adequately designed and executed clinical trials, it did not require contraindication in patients without a gallbladder.

32. The original May 2015 Viberzi Prescribing Label provided for two dosing regimens: 1) 100 mg twice daily; and 2) 75 mg twice daily for those patients who, inter alia, do not have a gallbladder.

33. On March 15, 2017, the FDA issued a Drug Safety Communication advising Viberzi should not be prescribed for patients without a gallbladder due to the risk of pancreatitis that could result in hospitalization or death. The FDA communication discussed 120 serious cases of pancreatitis, 27 of which resulted in hospitalization and 2 in death. The FDA noted that of the 84 cases reporting a time to onset, 48 occurred after only one or two doses of Viberzi.

34. On April 17, 2017, the Viberzi Prescribing Label was changed to contraindicate Viberzi use in patients without a gallbladder.

35. Plaintiff was 46 years old when she was prescribed Viberzi in September 2016.

36. At the time of Plaintiff's prescription, the Viberzi label contained no contraindication for patients without gallbladders.

37. Plaintiff had previously undergone a cholecystectomy.

38. Prior to September 2016, Defendants knew or should have known that Viberzi use in patients without gallbladders could cause or was causally associated with acute pancreatitis.

39. Prior to September 2016, Defendants had received numerous spontaneous reports of acute pancreatitis and/or SOD, the vast majority of which were dosed at 75 mg, indicating use by patients with prior cholecystectomies.

40. Prior to September 2016, the European Medicines Agency (EMA) informed Defendants that it would contraindicate Truberzi (the company's name for Viberzi in Europe) use in patients without a gallbladder. Discussing the decision on July 21, 2016, the EMA noted:

> A more confident conclusion that the occurrence of SO-spasm events can be reduced can be drawn if cholecystectomy is labeled as a contraindication because no such event was observed in a population with intact biliary tract. . . . Given the limited clinical relevance of the efficacy results, all populations at increased risk of SO-spasm and

> pancreatitis (with previous such disease, high alcohol intake and without gall-bladder) are consequently excluded from the treatment. This assumption has found preliminary confirmation through the evaluation of the early post-marketing data from the US (where no such contra-indication is imposed) and which show reports of pancreatitis and/or SO-spasm events, with their overwhelming majority affecting patients without gall-bladder.

41. Plaintiff took her one and only dose of Viberzi on September 21, 2016. She was admitted to Huntington Hospital (Huntington) the same day. Lab tests and imaging confirmed pancreatitis.

42. Plaintiff remained hospitalized for four days. She was discharged on September 24, 2016. Viberzi was discontinued as it was believed to be the cause of Plaintiff's event.

43. Plaintiff continues to suffer health consequences from her initial pancreatic event.

44. An episode of pancreatitis increases a patient's risk that she will later develop pancreatic cancer. Fear of developing pancreatic cancer subsequent to pancreatitis is reasonable.

45. Plaintiff remains at an increased risk for recurrent acute pancreatitis and/or chronic pancreatitis and pancreatic cancer, which she fears, and she continues to be monitored for health issues.

FEDERAL REQUIREMENTS

46. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Viberzi.

47. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

48. With respect to Viberzi, the Defendants, upon information and belief, has or may

have failed to comply with all federal standards applicable to the sale of prescription drugs, including, but not limit to, one or more of the following violations:

(a) Viberzi is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false and/or misleading;

(b) Viberzi is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. §352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(c) Viberzi is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

(d) Viberzi is misbranded pursuant to 21 U.S.C. §352 because it is dangerous to patient health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

(e) Viberzi does not contain adequate directions for use pursuant to 21 CFR §201.5 because, among other reasons, the omission, in whole or in part, or incorrect specification of (1) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed,

or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used, (2) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different physical conditions, (3) frequency of administration or application, (4) duration of administration or application, and/or (5) route or method of administration or application;

(f) Defendants violated 21 CFR §201.56 because the labeling was not informative and accurate;

(g) Viberzi is misbranded pursuant to 21 CFR §201.56 because the labeling was not updated as new information became available causing the labeling to become inaccurate, false, and/or misleading;

(h) Defendants violated 21 CFR §201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Viberzi causing pancreatitis;

(i) Defendants violated 21 CFR §201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took Viberzi;

(j) Viberzi is mislabeled pursuant to 21 CFR §201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

(k) Viberzi violates 21 CFR §210.122 because the labeling and packaging materials do not meet the appropriate specifications;

(l) Viberzi violates 21 CFR §211.198 because the written procedures

describing the handling of all written and oral complaints regarding Viberzi were not followed;

(m) Viberzi violates 21 CFR §310.303 because Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

(n) Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associate with Viberzi as soon as possible or at least within 15 days of the initial receipt by Defendants of the adverse drugs experience;

(o) Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associate with Viberzi, and evaluating the cause of the adverse event;

(p) Defendants violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

(q) Defendants violated 21 CFR §312.32 because they failed to review all information relevant to the safety of Viberzi or otherwise received by Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from

foreign regulatory authorities that have not already been previously reported to the agency by the sponsor; and

(r) Defendants violated 21 CFR §§314.80 by failing to provide periodic reports to the FDA containing (1) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (2) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

49. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants liable under California law.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

50. The running of any statute of limitation has been tolled by reason of Defendants' fraudulent conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with taking Viberzi.

51. As a result of Defendants' actions, Plaintiff and Plaintiff's prescribing physicians were unaware and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the Defendants' acts and omissions.

52. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the truth. Defendants were under a duty to disclose

the true character, quality and nature of Viberzi because this was non-public information over which Defendants had and continue to have exclusive control, and because Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers and/or to Plaintiff's health facilities. In addition, Defendants are estopped from relying on any statute of limitation because of their intentional concealment of these facts.

53. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and Plaintiff's medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

COUNT ONE:
STRICT LIABILITY - FAILURE TO WARN

54. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

55. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, inspected, labeled, distributed, sold, marketed, promoted and/or introduced Viberzi into the stream of commerce and in the course of same, directly advertised or marketed Viberzi to consumers or persons responsible for consumers and, therefore, had a duty to warn of the risk associated with the use of Viberzi, which they know or have reason to know and are inherent in the use of pharmaceutical products.

56. Viberzi was in a defective condition and unreasonably dangerous at the time that it left the control of the Defendants.

57. Due to the unreasonably dangerous condition of Viberzi, Defendants are strictly liable to Plaintiff.

58. Viberzi was under the exclusive control of Defendants and was not accompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of Viberzi, nor with adequate warnings regarding the risk of acute pancreatitis and other severe and permanent injuries associated with its use, nor with a contraindication of the use of Viberzi in patients who had previously had their gallbladder removed.

59. Defendants downplayed the serious and dangerous side effects of Viberzi to encourage sales of the product, placing profits above customers' safety.

60. Defendants failed to timely and reasonably warn of material facts regarding the risks of Viberzi in patients who had no gallbladder, and Viberzi would not likely have been prescribed or used had those facts been made known to such providers and Plaintiff.

61. Defendants' warnings were overwhelmed, downplayed and otherwise suppressed by Defendants' advertisement campaign, which did not demonstrate that Viberzi presented dangerous medical risks.

62. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field. Further, Defendants had knowledge of the dangerous risks and side effects of Viberzi.

63. Plaintiff did not have the same knowledge as Defendants and no adequate warning or contraindication was communicated to Plaintiff's physicians.

64. Had an adequate warning and/or contraindication been communicated to Plaintiff's physician, her physician would not have prescribed Viberzi and/or her physician

would have passed the warning/contraindication on to the Plaintiff and Plaintiff would not have used Viberzi.

65. Defendants had a continuing duty to warn consumers, including Plaintiff, Plaintiff's physicians and the medical community of the dangers associated with Viberzi. By negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

66. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT TWO:
STRICT LIABILITY - DEFECTIVE DESIGN

67. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

68. Viberzi was expected to and did reach the intended consumers, handlers and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled and marketed by Defendants.

69. At all times relevant, Viberzi was manufactured, designed and labeled in an

unsafe, defective and inherently dangerous condition, which was dangerous for use by the public and in particular, by Plaintiff.

70. Viberzi, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Viberzi.

71. Viberzi, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation because when it left the hands of Defendants' manufacturers and suppliers it was unreasonably dangerous and was also more dangerous than the ordinary consumer would expect.

72. At all times herein mentioned, Viberzi was in a defective condition and unsafe and Defendants knew and/or had reason to know that their product was defective and inherently unsafe, especially when Viberzi was used in a form and manner instructed and provided by Defendants.

73. At the time of Plaintiff's use of Viberzi, it was being used for its intended purpose and in a manner normally intended.

74. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common and intended use.

75. Due to the unreasonably dangerous condition of Viberzi, Defendants are strictly liable to Plaintiff.

76. Viberzi, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was manufactured defectively because Viberzi left the hands of Defendants in a defective condition and was unreasonably dangerous for the intended use for which it was manufactured and sold.

77. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that created an unreasonable risk to the health of consumers and to Plaintiff in particular. Therefore, Defendants are strictly liable for the injuries and damages sustained by Plaintiff.

78. Plaintiff could not have discovered, by the reasonable exercise of care, Viberzi's defects and perceived its danger.

79. Viberzi, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective due to inadequate warnings and contraindications. Since Defendants knew or should have known that Viberzi created an increased risk of acute pancreatitis and other serious and severe personal injuries, which are permanent and lasting in nature, Defendants failed to adequately test for and warn of these risks.

80. Viberzi, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective by design because Defendants were aware at the time it was marketed that Viberzi would cause an increased risk of acute pancreatitis in persons without gallbladders.

81. Viberzi, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because Defendants knew or should have known of the increased risk of acute pancreatitis.

82. By reason of the foregoing, Defendants are strictly liable in tort to Plaintiff.

83. Defendants' defective design of Viberzi and their over marketing through advertisements, together with the provision of inadequate warnings and contraindications accompanying Viberzi, were acts that amount to willful, wanton and/or reckless conduct by

Defendants.

84. The defects in Defendants' product were substantial and contributing factors in causing Plaintiff's injury.

85. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT THREE:
NEGLIGENCE

86. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

87. Defendants had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of Viberzi, including a duty to assure that Viberzi did not cause unreasonable, dangerous side-effects to users.

88. Defendants failed to exercise ordinary care in the manufacture, labeling, sale, marketing, quality assurance, quality control and distribution of Viberzi into the stream of commerce, in that the Defendants knew or should have known that the drug created a high risk of unreasonable harm in patients without gallbladders.

89. The negligence of the Defendants, their agents, servants and/or employees included, but was not limited to, the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, developing, designing, assembling, selling and distributing Viberzi without thorough and adequate testing;

(b) Manufacturing, producing, promoting, advertising, formulating, creating, developing, designing, assembling and distributing Viberzi while concealing and suppressing test results;

(c) Not conducting sufficient studies and tests to determine whether Viberzi was safe for its intended use, because Defendants knew or had reason to know that Viberzi was indeed unsafe and unfit for use by reason of the dangers it presents to users;

(d) Failing to warn Plaintiff, the medical and healthcare community, including Plaintiff's physicians, the general public, and/or the FDA as soon as Defendants knew or should have known of the dangers of the use of Viberzi in patients without gallbladders;

(e) Concealing, suppressing, failing to warn about and/or failing to follow up on the adverse results of clinical testing that occurred, which indeed indicated that Viberzi had a high risk of serious and dangerous adverse health effects and consequences;

(f) Failing to provide a contraindication for the use of Viberzi in patients without gallbladders;

(g) Advertising and recommending the use of Viberzi while suppressing and concealing its known dangers;

(h) Representing that Viberzi was safe for its intended use when it was actually unsafe for its intended purpose in patients without gallbladders;

(i) Suppressing, concealing, omitting and/or misrepresenting information to Plaintiff, the medical community and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of Viberzi in patients without gallbladders; and

(j) Failing to conduct adequate post-marketing surveillance to determine the safety of Viberzi, failing to comply with post-marketing requirements of FDA regulations, failing to perform adequate Pharmacovigilance, and otherwise careless or negligent acts.

90. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of Viberzi, including Plaintiff, by suppressing this knowledge from the general public.

91. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT FOUR:
NEGLIGENT MISREPRESENTATION

92. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

93. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public, that Viberzi had been tested and found to be safe and effective for all persons who suffered from irritable bowel syndrome with diarrhea. The representations made by Defendants, in fact, were false.

94. Defendants failed to exercise ordinary care in the representations concerning Viberzi while they were involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented Viberzi was safe and effective for all persons who suffered from irritable bowel syndrome with diarrhea.

95. Defendants breached their duty in representing that Viberzi was safe and effective for all persons who suffered from irritable bowel syndrome with diarrhea.

96. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT FIVE:
BREACH OF EXPRESS WARRANTY

97. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

98. Defendants expressly warranted in their manufacturing, design, distribution, marketing and promotion of Viberzi that Viberzi was safe, effective and fit for use by Plaintiff and members of the consuming public generally, that it was of merchantable quality, that its side effects were minimal in all persons for whom it was indicated, including Plaintiff, and that it was adequately tested and fit for its intended use.

99. At the time of making such express warranties, Defendants knew or should have known that Viberzi did not conform to these express representations because Viberzi is not safe for its intended use in persons without gallbladders as it could cause them to suffer pancreatitis and its sequelae, and was thus unreasonably unsafe for its intended purpose.

100. As a foreseeable, direct and proximate result of the breach of these warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

101. Plaintiff did rely on the express warranties of Defendants with respect to Viberzi.

102. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of Viberzi.

103. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendants in connection with the use, recommendation, description and/or dispensing of Viberzi.

104. Defendants expressly represented to Plaintiff, Plaintiff's physicians and healthcare providers that Viberzi was safe and fit for the purposes intended, that it was of merchantable

quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

105. Defendants knew or should have known that their representations and warranties were false, misleading and untrue because Viberzi was not safe and fit for its intended use, Viberzi did not conform to these express warranties and representations (including the representation that it was safe, the representation that it did not have high and/or unacceptable levels of life-threatening side effects, and the representations that are otherwise set forth in this complaint and/or in Defendants' promotional and marketing materials) and Viberzi caused its users without gallbladders serious injuries, and this was not adequately identified and represented by Defendants.

106. At the time of the making of these express warranties, the Defendants had knowledge of the purpose for which Viberzi was to be used and warranted same to be in all respects safe, effective and proper for such purpose.

107. Viberzi does not conform to these express warranties and representations because it is not safe or effective in persons without gallbladders and may produce serious side effects, including acute pancreatitis.

108. Plaintiff is informed and believes that Plaintiff will be required to have further medical and/or hospital care, attention and services.

109. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT SIX:
BREACH OF IMPLIED WARRANTY
OF MERCHANTABILITY

110. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

111. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Viberzi for the treatment of irritable bowel syndrome with diarrhea.

112. Defendants marketed, sold and distributed Viberzi, knew and promoted the use for which Viberzi was being used by Plaintiff, and impliedly warranted to Plaintiff that Viberzi was of merchantable quality and fit for the ordinary purpose for which it was intended, namely treating irritable bowel syndrome with diarrhea.

113. These representations and warranties were false, misleading and inaccurate in that Viberzi was unsafe and compromised Plaintiff's health.

114. Plaintiff reasonably relied upon the skill, expertise and judgment of the Defendants and their representations that Viberzi was of merchantable quality.

115. The Viberzi manufactured and sold by Defendants was not of merchantable quality as warranted by Defendants in that the drug had dangerous and life-threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

116. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering, and economic loss.

117. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT SEVEN:
BREACH OF IMPLIED WARRANTY
OF FITNESS FOR A PARTICULAR PURPOSE

118. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

119. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Viberzi for the treatment of irritable bowel syndrome with diarrhea.

120. Defendants impliedly represented and warranted to the users of Viberzi that Viberzi was safe and fit for the particular purpose for which said product was to be used, namely the treatment of irritable bowel syndrome with diarrhea.

121. Defendants are sellers of and merchants with respect to Viberzi.

122. These representation and warranties were false, misleading and inaccurate in that Viberzi was unsafe and compromised Plaintiff's health.

123. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

124. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Viberzi was safe and fit for its intended use.

125. Viberzi was injected into the stream of commerce by the Defendants in a defective, unsafe and inherently dangerous condition, and the products and materials were expected to and did reach users, handlers and persons coming into contact with said products without substantial change in the condition in which they were sold.

126. Defendants breached the aforesaid implied warranty as Viberzi was not fit for its intended purposes and uses.

127. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT EIGHT:
PUNITIVE DAMAGES

128. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

129. Viberzi was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed and released into the stream of commerce by

Defendants and/or each of them after Defendants knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of Viberzi in patients without gallbladders.

130. The acts, conduct, and omissions of Defendants as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Viberzi users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Viberzi. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

131. Prior to the manufacturing, sale, and distribution of Viberzi, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Viberzi.

132. Despite its knowledge, Defendants, acting through its officers, directors and managing agents, for the purpose of enhancing Defendants' profits knowingly and deliberately failed to remedy the known defects in Viberzi and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Viberzi. Defendants and their agents, officers and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of Viberzi knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

133. The aforesaid conduct of Defendants was committed with knowing, conscious

indifference, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

134. Defendants' actions showed willful misconduct, malice, fraud, wantonness, oppression, and/or the entire want of care raises the presumption of conscious indifference to the consequences.

135. When warning of risks of Viberzi, Defendants recklessly and/or fraudulently represented to the medical and healthcare community, the FDA, Plaintiff and the public in general that Viberzi had been tested and was found to be safe and/or effective for its indicated use, including in patients without gallbladders.

136. Defendants concealed their knowledge of Viberzi's defects from Plaintiff, the FDA, the public in general and/or the medical community specifically.

137. Defendants maliciously concealed their knowledge of the defects in Viberzi from Plaintiff and Plaintiff's physicians, hospitals, pharmacists, the FDA and the public in general.

138. Defendants knowingly withheld or misrepresented information required to be submitted under the FDA's regulations, which information was material and relevant to the harm in question.

139. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly

and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants as follows:

a. Awarding compensatory damages resulting from Defendants' violation of their duties;

b. Awarding compensatory damages resulting from Defendants' breach of warranties;

c. Awarding medical monitoring damages to Plaintiff;

d. Awarding actual damages to Plaintiff incidental to Plaintiff's purchase and use of Viberzi in an amount to be determined at trial;

e. Awarding punitive damages to Plaintiff;

f. Awarding pre-judgment and post-judgment interest to Plaintiff;

g. Awarding the costs and the expenses of litigation to Plaintiff;

h. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

i. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

/s/ Levi M. Plesset
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